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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/826,112

04/17/2004

Reuben Matalon

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EXAMINER

FINN, MEGHAN R

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

03/17/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/826,112	Applicant(s) MATALON, REUBEN	
	Examiner MEGHAN FINN	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 57,59 and 61-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 57,59,61-71 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's Amendment filed December 29, 2010 has been received and entered into present application. No claims were canceled and claim 71 was added by applicant. Thus claims 57, 59, and 61-71 are pending.

Applicants' arguments, filed December 29, 2010, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

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consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 57, 59, 61-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wachtel et al. (DE 4037447 A1, translation provided previously), already of record, for the reasons set forth at pages 3-6 of the previous office action dated July 29, 2010 the reasons of which reasons are herein incorporated by reference.

Applicant has added a new claim 71, which depends on claim 57 and specifies that the composition is to be used at mealtime. This is an intended use of the composition; any composition comprising the same components is capable of being used at meal time. Thus the previous rejection over claim 57 applies to the new claim 71 as well because the same composition is capable of being used at mealtime. Applicant has not amended any of the previously presented claims. Applicant has argued that the claims are not obvious over Wachtel et al. because Wachtel et al. is directed towards a product to be used by PKU patients and does not teach or suggest that the PKU patients could be treated in order to control the uptake of Phe from the normal diet. They also argue that Wachtel et al. does not teach using increased amounts of amino acids which compete with Phe for GI tract uptake and the reasoning in Wachtel et al. is not the same as the present invention. As mentioned in the previous office action, the claims are directed towards a composition. The prior art is not required to teach the same reason or have the same motivation. They do not even need to treating the same patient population, although Wachtel et al. actually does. They

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only need to teach the composition and the composition claimed by applicant is obvious over Wachtel et al. as explained in the previous two office actions. Applicant has again submitted that Pietz et al. is closer prior art. As mentioned in the previous office action, the claims are directed towards a composition, and thus the closest prior art is the closest composition, not a reference which teaches treating the same problem with a composition that less similar to the claimed composition. **The fact that the composition of Wachtel et al. is closer to the claimed composition than Pietz et al. makes it necessarily the closest prior art.** Applicant then goes on to compare their invention to Pietz et al. and attempts to establish unexpected results. Applicant must compare their invention to the closest prior art, Wachtel et al. in order to demonstrate unexpected results. The fact that their invention works better than the composition of Pietz (Prekuniil®) is not evidence of unexpected results. Applicant has further submitted studies showing the effectiveness of their composition but never compares it to a composition such as that of Wachtel et al. and thus has not demonstrated unexpected results.

Applicant's argument has been carefully and fully considered however is not deemed persuasive and thus the rejection of claims 57, 59, and 61-70 is **maintained.** New rejection of claim 71 is necessitated by the amendment to the claims.

Conclusion

Rejection of claims 57, 59, and 61-70 is deemed proper and is **maintained.**

Rejection of newly added claim 71 is necessitated by amendment.

No Claims of the present application are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

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USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Meghan Finn whose telephone number is (571) 270-3281. The examiner can normally be reached on 8:30am-6pm Mon-Thu, 8:30am-5pm Friday (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Meghan Finn

/Leslie A. Royds Draper/
Primary Examiner, Art Unit 1614